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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/844,815	04/30/01	REHM G	MSE #2610

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EXAMINER	
COUNTS, G	
ART UNIT	**PAPER NUMBER**
1641	2

DATE MAILED: 10/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/844,815	Applicant(s) REHM ET AL.	
	Examiner Gary W. Counts	Art Unit 1641	

-- Th MAILING DATE of this communication appears on th cov r she t with the correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, drawn to an assay for trypsin inhibitors, classified in class 435, subclass 174.

II. Claims 11-14, drawn to a method for preparing a test device for the determination of trypsin inhibitors in urine, classified in class 435, subclass 69.2.

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant, the assay of invention I involves correlating the concentration of trypsin inhibitor with the detectable response from cleaving of the substrate and involves the use of an aqueous or polar aprotic solvent whereas invention II involves the use of non-ionic polyoxyalkyl surfactant and does not involve correlating the concentration of trypsin inhibitor with the detectable response from cleaving of the substrate or the use of an aqueous or polar aprotic solvent.

1. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the

search required for one group is not required for other restriction for examination purposes as indicated is proper.

During a telephone conversation with Jerome L. Jeffers on 09-24-01 a provisional election was made with traverse to prosecute the invention of group I, claims 1-10. Affirmation of this election must be made by applicant in replying to this Office action. Claims 11-14 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2, line 1 "the assay reagents" there is insufficient antecedent basis for this limitation. See also deficiency found in claim 5, line 1.

Claim 3, line 1 "the solvent" there is insufficient antecedent basis for this limitation. See also deficiency found in claim 4, line 1. Claim 3, line 2 "the solution" there is insufficient antecedent basis for this limitation.

Claim 5, line 1 "the dry phase" there is insufficient antecedent basis for this limitation.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-4, and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uenoyama et al (US Patent 5,856,117) in view of Berry et al (US Patent 5,384,247).

Uenoyama et al disclose a method for measuring the concentration of urinary trypsin inhibitors which involves mixing an urine sample, trypsin, and a buffer solution and the addition of a substrate solution to cause the enzyme reaction, and measuring the activity of trypsin (col 5, lines 39-60). Uenoyama et al also teach the use of dimethylfomamide as the solvent (col 6, line 11) and a buffered pH of 7.8 (col 7, line 46) and the substrate present in a concentration of 1 to 50 mmol/l (col 4, line 16) and trypsin in the concentration of 10 to 500 mg/l preferably 20 to 100 mg/l (col 5, line 52).

The method of Uenoyama et al differs from the instant invention in failing to disclose the use of a polycarboxylic chelating agent to inhibit interference of calcium present in the urine.

Berry et al (US Patent 5,384,247) teach the use of EGTA and EDTA as chelating agents which inhibit the interfering ions of calcium in a urine sample (col 5, lines 19-39, col 6, line 14-17). The use of these chelating agents reduce the free concentration of interfering ions to levels where interference is no longer significant and increase the sensitivity of the enzyme to an analyte with respect to the interfering ion (col 3, lines 45-52).

It would have been obvious to one of ordinary skill in the art to incorporate the polycarboxylic chelating agents of Berry et al into the method of Uenoyama et al because Berry et al shows that the use of these chelating agents provide the advantage of reducing the free concentration of interfering ions to levels where interference is no longer significant and also increase the sensitivity of the enzyme to an analyte.

With respect to the specific concentration of the chelating agents recited in the instant claims, the optimum concentration of chelating agent can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art.

6. Claims 5 and 6 rejected under 35 U.S.C. 103(a) as being unpatentable over Uenoyama et al in view of Berry et al as applied to claims 1-4 and 7-9 above, and further in view of May et al (GB 2,204,398 A).

See above for teachings of Uenoyama et al and Berry et al.

Uenoyama et al differ from the instant invention failing to disclose dry test reagents and a dry test device which the urine test sample can flow by dipping the dry test device into the buffered assay medium.

May et al disclose a device comprising a hollow casing constructed of moisture-impervious solid material containing a dry porous carrier which communicates indirectly with the exterior of the casing, a sample receiving member protrudes from the casing such that a liquid test sample can be applied to the receiving member and permeate to the porous carrier which contains impregnated reagents (page 15, lines 16-35 and page 16, lines 1-9). This diagnostic test device allows for quick and convenient use and requires the user to perform as few actions as possible (page 2, lines 29-35).

It would have been obvious to one of ordinary skill in the art to use the device of May et al to practice the method of Uenoyama et al as modified by Berry et al, because May et al shows that the device allows for quick and convenient use and requires the user to perform as few actions as possible, where all the necessary reagents are all present on a single solid support.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ueoyama et al in view of Berry et as applied to claims 1-4 and 7-9 above, and further in view of Nanbu et al (US Patent 6,130,055).

See above fro teachings of Uenoyama et al and Berry et al.

Uenoyama et al differ from the instant invention in failing to disclose arginine or lysine derivatives as the substrate for trypsin.

Nanbu et al discloses a method for measuring the concentration or activity of urinary trypsin inhibitor. Nanbu et al teach mixing a sample, trypsin solution, and a substrate in a solution and measuring the tryspin activity. Nanbu et al also teach that this substrate may come from the amino acid residues of the L-type (col 2, lines 13-23). The use of this substrate would allow for excellent solubility.

It would have been obvious to one of ordinary skill in the art to incorporate the trypsin substrates of Nanbu et al into the method of Uenoyama et al as modified by Berry et al because Nanbu et al shows that the use of the L-type amino acid residues allows for excellent solubility (col 2, line 23).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Vallieres et al (US Patent 5,595731) disclose the use of chelating agents in order to remove at least the ionized part of calcium from urine (col 2, lines 61-67).

Yonehara et al (US Patent 6,177,268) disclose a method of preparing a reagent for use in measuring the enzymatic activity of trypsin and the drying of the stabilized trypsin solution (col 4, lines 4-15).

Nonobe et al (US Patent 5,618,684) disclose the use of EDTA as a chelating reagent (col 4, lines 31-45).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary W. Counts
Examiner
Art Unit 1641
October 9, 2001

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/1641